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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,371	10/12/2000	Matthew Cotten	0652.2150001/EKS/PAJ	5877

7590                    03/13/2002  
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[REDACTED] EXAMINER

FOLEY, SHANON A

[REDACTED] ART UNIT            [REDACTED] PAPER NUMBER  
1648

DATE MAILED: 03/13/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/688,371	COTTEN ET AL.
	Examiner	Art Unit
	Shanon A. Foley	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is FINAL. 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1-40 is/are pending in the application.
  - 4a) Of the above claim(s) 17-40 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-16 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10,13.
- 4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 15 is acknowledged. The traversal is on the ground(s) that no serious burden to search all pending claims has been established since searches for the products and methods of making the product, and the method of using the product as a vaccine are co-extensive for groups I-IV. Applicant requests examination of claims 35-40 if the product claims in group I are found to be allowable.

This is not found persuasive because a search burden has been established for all groups I-VII as evidenced by their separate classification in the art. As discussed in the previous Office action, the product of group I can be made by at least three materially distinct processes in groups II-IV. Each of the methods requires different components and method steps that make each process patentably distinct from the other. Applicant's request for further examination of groups VII upon allowability of the product in group I has been considered and is accepted.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups II-VII, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

### ***Drawings***

The drawings of Figures 1A-1C are objected to because there is no description of these drawings in the "Brief Description of the Drawings" section. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 states that the foreign DNA is a tumor antigen or a "fragment thereof". The metes and bounds of what is considered a "fragment thereof" has not been described.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 8, 16, 20-28, 30-34, 81, 83, and 149-162 of U.S. Patent No. 6,335,016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the mutated regions in the patent are overlapping with the regions in the instant application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999

(AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by

Michou et al. (Journal of Virology. Feb. 1999; 73 (2): 1399-1410).

The claims are drawn to a recombinant CELO virus or CELO virus DNA that has a deletion spanning nt 36818-37972 and 37391-38239 that inhibits functional expression of Gml and contains a foreign gene insert in place of the deleted region.

Michou et al. teaches recombinant CELO genome construct, pAIM45, that has nt deletions spanning 33358-43684 and expresses the luciferase gene in place of the deleted sequences, see Table 2 on page 1401 and Figure 3 on page 1403. The construct is expressed on a plasmid that replicates in *E. coli*, see the second column on page 1402. Although Michou

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et al. does not expressly teach that Gam1 expression is inhibited in the construct, this feature would be an inherent characteristic since the region spanning Gam1 expression is deleted.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Baker et al. (WO 97/40180, translation provided in IDS of paper no. 13).

The claims are drawn to a recombinant CELO virus or CELO virus DNA that has a deletion spanning nucleotide sequences that inhibits functional expression of Gam1. The recombinant additionally contains deletions of nucleotides between 794-1330 and 40065-43684 and contains a foreign gene insert in place of the deleted region.

Baker et al. teaches a CELO virus deleted between nucleotides 31, 800 – 43, 734 and 794 - 1330, which are suitable site for foreign DNA insertion. The foreign DNA encodes for an animal pathogen, an avian pathogen, a human protein, a therapeutically active protein, an immunostimulatory protein, a cytokine, a human pathogen, or a tumor antigen, see claims 1-13, and 16. The CELO virus of Baker et al. expressed by a plasmid which is replicable in bacteria, yeast, or bird embryo kidney or liver cell lines, see page 11, lines 15-19.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Baker et al. (US 6,335,016).

The claims are drawn to a recombinant CELO virus or CELO virus DNA that has a deletion spanning nucleotide sequences that inhibits functional expression of Gam1. The recombinant additionally contains deletions of nucleotides between 794-1330 and 40065-43684 and contains a foreign gene insert in place of the deleted region.

Baker et al. teaches a CELO virus deleted between nucleotides 31, 800 – 43, 734 and 794 - 1330, which are suitable site for foreign DNA insertion. The foreign DNA encodes for an

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animal pathogen, an avian pathogen, a human protein, a therapeutically active protein, an immunostimulatory protein, a cytokine, a human pathogen, or a tumor antigen, see claims 1, 4, 5, 8, 16, 20-28, 30-34, 81, 83, and 149-162. The CELO virus of Baker et al. expressed by a plasmid which is replicable in bacteria, yeast, or bird embryo kidney or liver cell lines, see column 6, lines 3-7.

Although neither Baker et al. reference expressly teaches that Gam1 expression is inhibited in the construct, this feature would be an inherent characteristic since the region spanning Gam1 expression is deleted.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983.

The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*SAF*  
Shanon Foley/SAF  
March 7, 2002

*James C. Housel*  
JAMES HOUSEL 3/1/02  
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